

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, October 6, 2025  
**Time:** 1:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Wayne State University, Detroit, MI  
**Principal Investigator:** Andrew D. Kin, MD  
**Protocol:** Poseida Therapeutics, Inc., P-CD19CD20-ALLO1-001  
**NCT Number:** NCT06014762  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** Open-Label, Multicenter, Phase 1 Study to Assess the Safety of P-CD19CD20-ALLO1 in Subjects with Selected Relapsed/Refractory B cell Malignancies

### 1. Call to order:

The Meeting was called to order at 1:00 pm Eastern Time.

### 2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

### 3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution and the Institution's Biosafety Officer. Also present were four Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

### 4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

### 5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

### 6. Approval of previous meeting minutes:

Minutes Approved - YES: 6 NO: 0 ABSTAIN: 0

### 7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

### **Points of Discussion:**

1. The Committee noted that the most recent Investigator's Brochure indicates that the study agent may also be provided to sites in a cryobag, and recommended that the Institution submit to IBC Services a more current Cell Therapy Lab and Administration Manual if one is available.
2. An Institutional Representative confirmed that no subjects have yet been dosed with the study agent.

### 8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for P-CD19CD20-ALLO1, since it consists of primary human cells modified using a plasmid and mRNA. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of P-CD19CD20-ALLO1 locally**, provided all other criteria for study closure are met. The Committee reaffirmed this determination.

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### **9. Vote on the Protocol:**

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6

NO: 0

ABSTAIN: 0

### **10. Review of proposed facilities and practices:**

The Chair provided an overview of the arrangement for the facilities and practices.

#### **Points of Discussion:**

1. If a newer Cell Therapy and Administration Manual is available with information about cryobag preparation and dosing, the Committee recommended that the Biosafety SOP Addendum for Allogenic Cells be revised accordingly.
2. An Institutional Representative confirmed that the Biological Safety Cabinets are certified every six months and the BSCs that will be used to prepare the study agent will be recertified this month.
3. The Committee discussed the IATA Shipping Training Certification and noted that it does not contain an expiration date, nor does it reference the ATA Dangerous Goods Regulations (DGR) version staff members are trained on. The Committee recommended that the Institution either provide a more thorough training certification or a Note to File from the Institution with details about the specific federal regulations shipping training covers.

### **11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

### **12. Vote on the Site:**

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6

NO: 0

ABSTAIN: 0

### **13. Advice to the Institution:** None.

### **14. Meeting adjourned:** The meeting was adjourned at 1:14 pm Eastern Time.